AMENDMENTS TO H.R. 6432

OFFERED BY MR. PALLONE OF NEW JERSEY

On page 2, line 21, strike ''that has not been withdrawn'' and insert ''that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary''.

On page 2, after line 21, insert the following (and renumber the succeeding paragraphs accordingly):

(2) in paragraph (8)(H), by striking ''but not such activities after an animal drug has been approved'' and inserting ''but not after such application has been approved'';

On page 4, lines 10 through 13, strike the phrase ''in fiscal year'' each place it appears and insert ''for fiscal year''.

On page 10, lines 8 and 9, strike ''Not less frequently than once every month'' and insert ''Not less frequently than once every 4 months''.

On page 10, lines 11 and 12, strike ''patient and consumer advocacy groups'' and insert ''veterinary, patient, and consumer advocacy groups''.

Amend section 5 of the bill to read as follows:

SEC. 5. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORTS.

(a) REPORTS.—Section 512(l) (21 U.S.C. 360b(l)) is amended by adding at the end the following:

''(3)(A) In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

''(B) Each report under this paragraph shall specify the amount of each antimicrobial active ingredient—

''(i) by container size, strength, and dosage form;

''(ii) by quantities distributed domestically and quantities exported; and

''(iii) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

''(C) Each report under this paragraph shall—

''(i) be submitted not later than March 31 each year;

''(ii) cover the period of the preceding calendar year; and

''(iii) include separate information for each month of such calendar year.

''(D) The Secretary may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act.

''(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—

''(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

''(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.''.

(b) FIRST REPORT.—For each new animal drug that is subject to the reporting requirement under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and for which an approval of an application filed pursuant to section 512(b) or 571 of such Act is in effect on the date of the enactment of this Act, the Secretary of Health and Human Services shall

require the sponsor of the drug to submit the first report under such section 512(l)(3) for the drug not later than March 31, 2010.

(c) SEPARATE REPORT.—The reports required under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be separate from periodic drug experience reports that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of the enactment of this Act).

Amend section 7 of the bill to read as follows:

SEC. 7. EFFECTIVE DATE.

The amendments made by sections 2, 3, and 4 shall take effect on October 1, 2008, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after such date, regardless of the date of the enactment of this Act.